



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Depyrogeneration Tunnel

SOP No.:		Department:	Production
		Effective Date:	
Revision No.:	00	Revision Date:	
Supersede Revision No.:	Nil	Page No.:	1 of 18

1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Depyrogeneration Tunnel.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Depyrogeneration Tunnel (Make: **Truiking Technology Ltd.**) in Ampoule line

3.0 RESPONSIBILITY:

Operator: To run the machine & perform the cleaning activity.

Officer/Executive: Production Officers and Executives are responsible to monitor and to ensure that all production personnel are following this SOP.

IPQA: IPQA are responsible for to ensure the compliance status of this SOP.

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
ID No.	Identification Number
IPA	Isopropyl Alcohol
MMI	Men Machine Interface
PLC	Programmable Logic Controller
QA	Quality Assurance
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 After completion of washing, following procedure takes place:

6.1.1 The ampoules enter the tunnel through the **in feed**.

6.1.2 After that the ampoules enter the **Drying zone** (Temp-80°).

6.1.3 Next the dried ampoules enter the **Heating zone** (Temp-320°).

6.1.4 Finally, the ampoules reach the **Cooling zone** (Temp.- 40°).

6.1.5 Next the ampoule reaches the **out feed** and enters into **filling area**.



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6.2 DEFINITION:

Depyrogeneration is removal or inactivation of microorganism including bacterial endotoxin.

6.3 PRECHECKS AND PRECAUTIONS:

6.3.1 Inspect all the utilities and check points before start of the operation.

6.3.2 Ensure the proper cleanliness of Equipment and area.

6.3.3 Ensure whether the blower suit is in on condition.

6.3.4 Ensure the DP is within the limit.

6.3.5 Take the Line clearance as per procedure.

6.3.6 Ensure the temp is within the limit.

6.3.7 Confirm the status sign of machine.

6.3.8 Make sure power indicator is green.

6.3.9 Open the valve of purified water for cooling the hot air fan.

6.3.10 Check whether air shutter between preheating zone and heating zone , heating zone to cooling zone is in closed status .if it doesn't adjust the position 5MM Higher than side plate.

6.3.11 Check whether air shutter in the outlet of cooling zone is in closed condition.

6.3.12 Check and ensure the Plexiglas doors of window in the chamber of preheating zone and cooling zone are in closed status.

6.4 PASSWORD LEVELS:

There are three password levels for operating the machine:-

Operator Level: This level is handled by the operator regarding operations i.e. batch details, operation parameters etc.

Supervisor Level: Level used to update the daily variables used in routine operations.

Manager/Admin Level: Level basically used for addition, deletion or modification of data.

6.5 TUNNEL RECIPE: The following are the parameters for tunnel recipe:

S.No.	Size of Ampoules	Capacity in Nos.
1.	1ML	25000
2.	2ML	22000
3.	3ML	18000
4.	5ML	15000



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6.6 TUNNEL SETTING:

6.6.1 Set the damper panel on in feed and out feed of sterilizing zone by turning the knobs.

6.6.2 Tunnel Temperature Parameters:- The parameters of tunnel are as follows:

S.No.	Zones	Temperature °C
1.	Preheating zone	80
2.	Heating zone 1	320
3.	Heating zone 2	320
4.	Heating zone 3	320
5.	Cooling zone 1	50
6.	Cooling zone 2	40
7.	Heating zone Overshoot	330
8.	Print internal (Sec)	60 (Sec)

6.6.3 Tunnel differential pressure: DP of 3 zone is as below as:

S.No.	Zones	Differential Pressure
1.	Preheating Zone	5-10 Pascal
2.	Heating zone	6-12 Pascal
3.	Cooling zone	5-10 Pascal

6.6.4 Tunnel Conveyer speed according to ampoule size:

S.No.	Size of ampoule	Conveyer speed (mm/min)
1.	1 ml	76
2.	2 ml	92
3.	3 ml	110
4.	5 ml	120

6.6.5 Tunnel Layout:

6.6.5.1 Total Length of tunnel : 4200 mm

6.6.5.2 Total width of tunnel : 620 mm

DRYING ZONE	HOT ZONE	COOLING ZONE
610 mm	1800 mm	1790 mm



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6.7 TUNNEL OPERATION:

6.7.1 Auto Mode:

6.7.1.1 Open the power switch. The arrow of switch points to right side and power electrifies at this time red alarm light on the equipment is on.



6.7.1.2 Switch on the recorder.

6.7.1.3 The touch screen displays the interface of first page.



6.7.1.4 Click the keyboard on the logon window and enter the user name and password to the system.



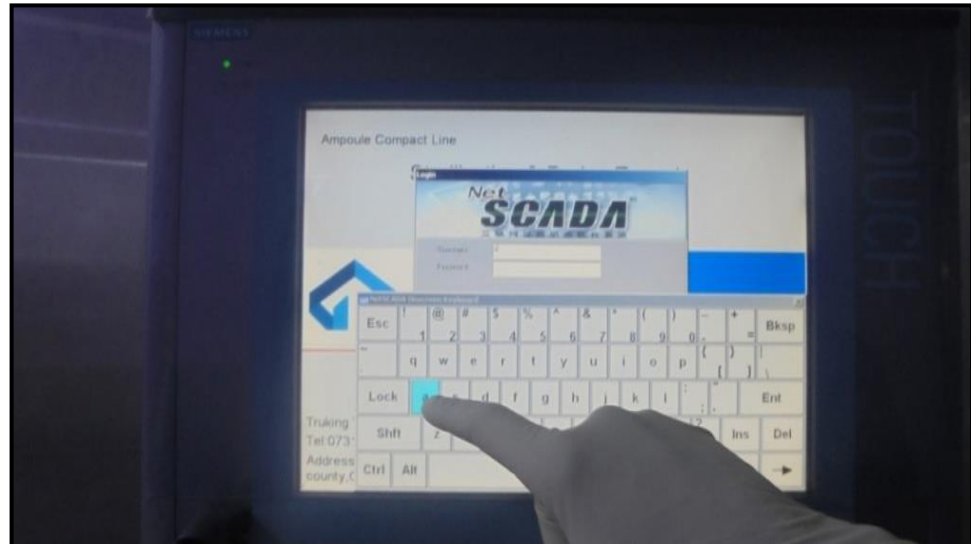
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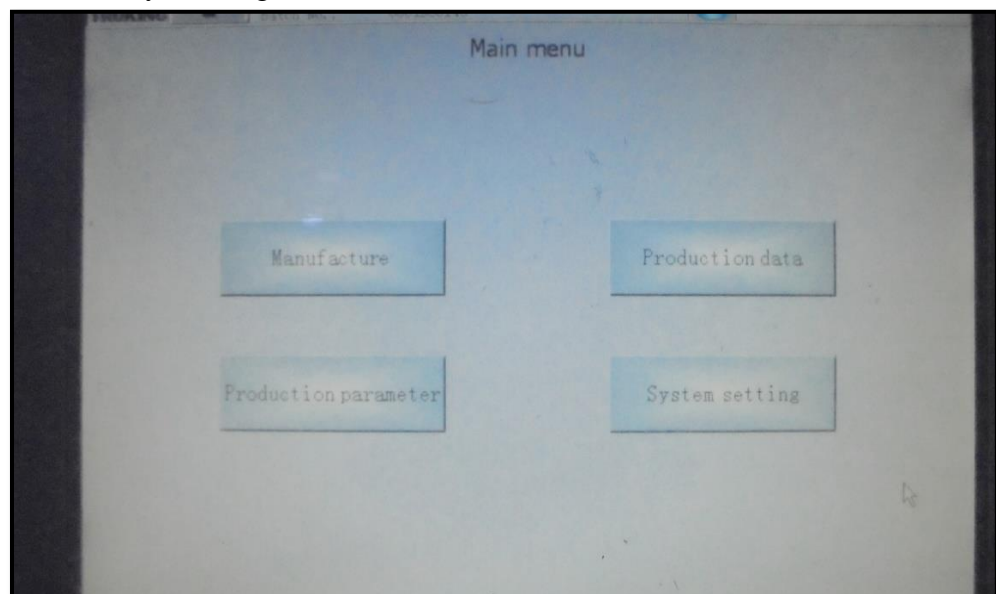
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6.7.1.5 User can access the main menu, it will appear the following buttons the user can access to different functions by clicking each button.



6.7.1.6 Click the **manufacture** button on the lower left side and access to the appropriate interface.



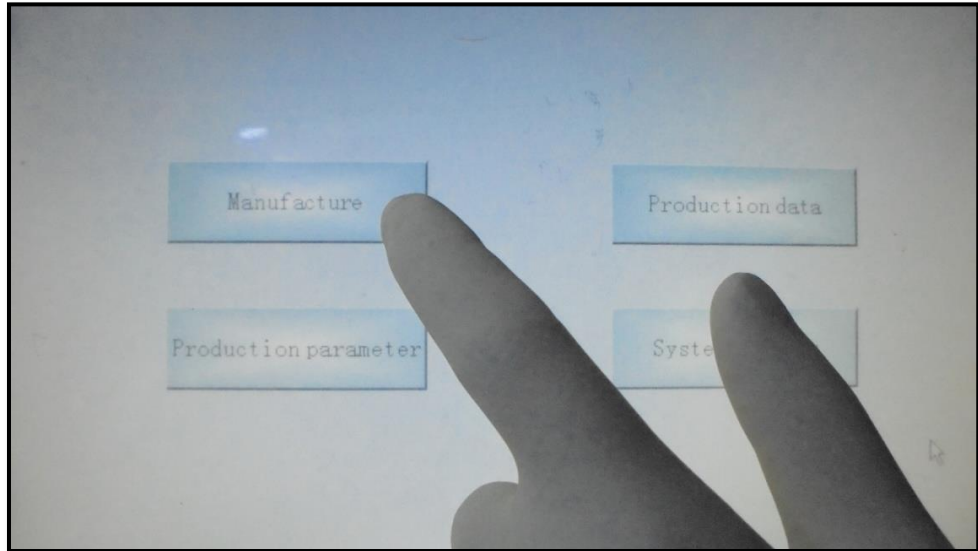
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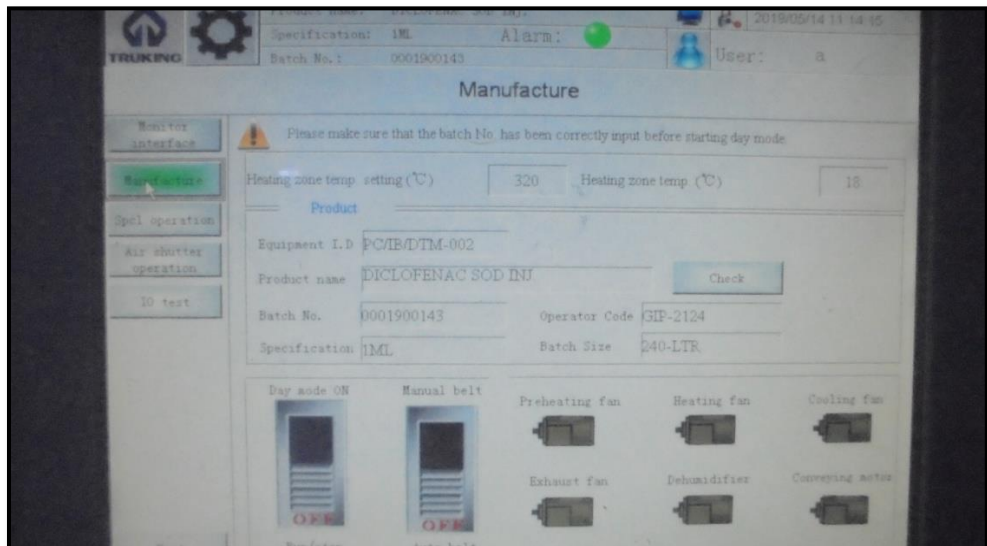
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6.7.1.7 Check and enter the product name, batch no and ensure the ampoule specification meet the product to be produced.



6.7.1.8 Back to the main operation interface, click the operation button.

6.7.1.9 Check opening mode of conveyor belt switches to mode automatic conveying ampoule whether temperature limit mode switches to conveying ampoule via limited condition.



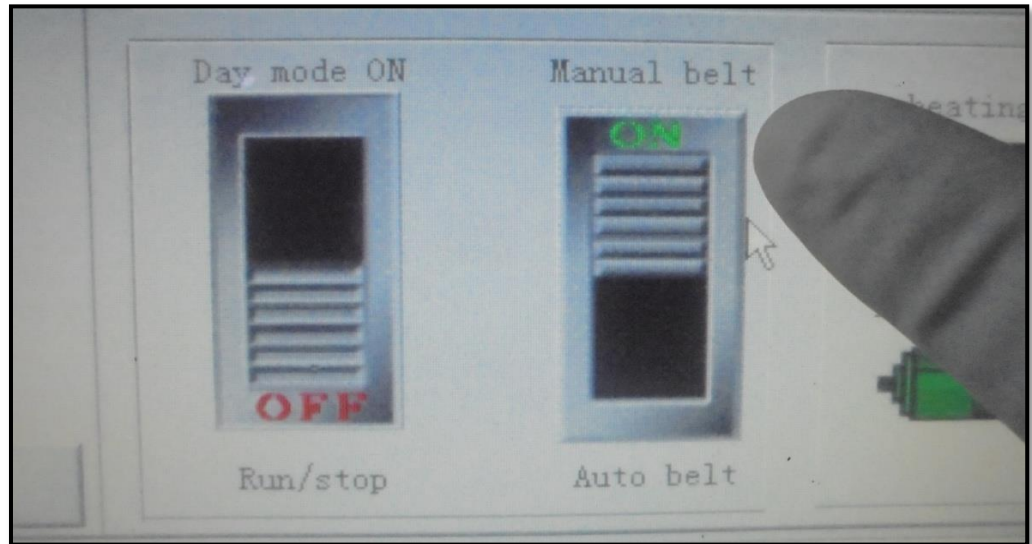
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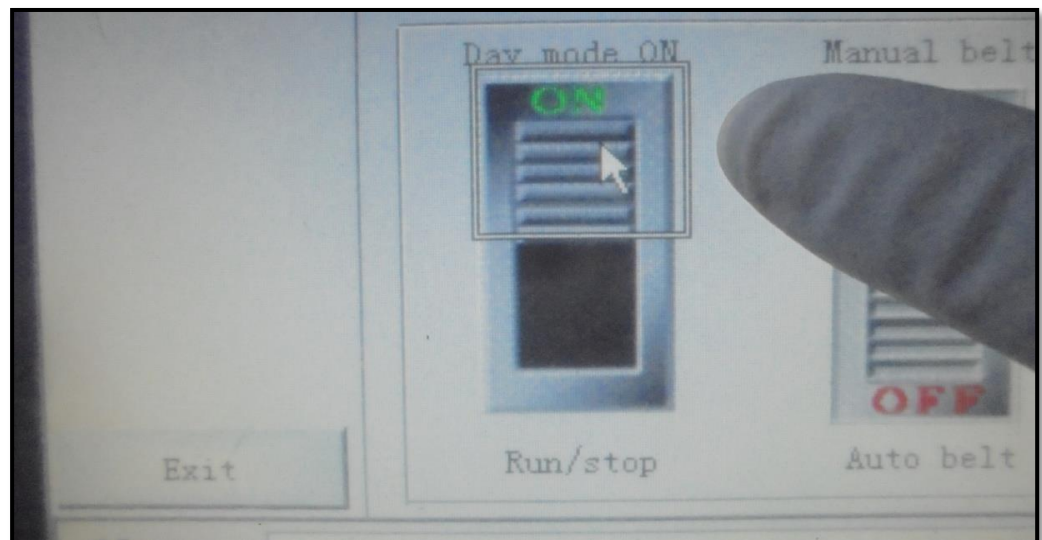
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6.7.1.10 Set the button on day mode in machine access program for temperature.



Note: Please check whether each fan is running normally without alarm.

6.7.2 Manual Mode:

6.7.2.1 Select the 'Special operation' option on the HMI.



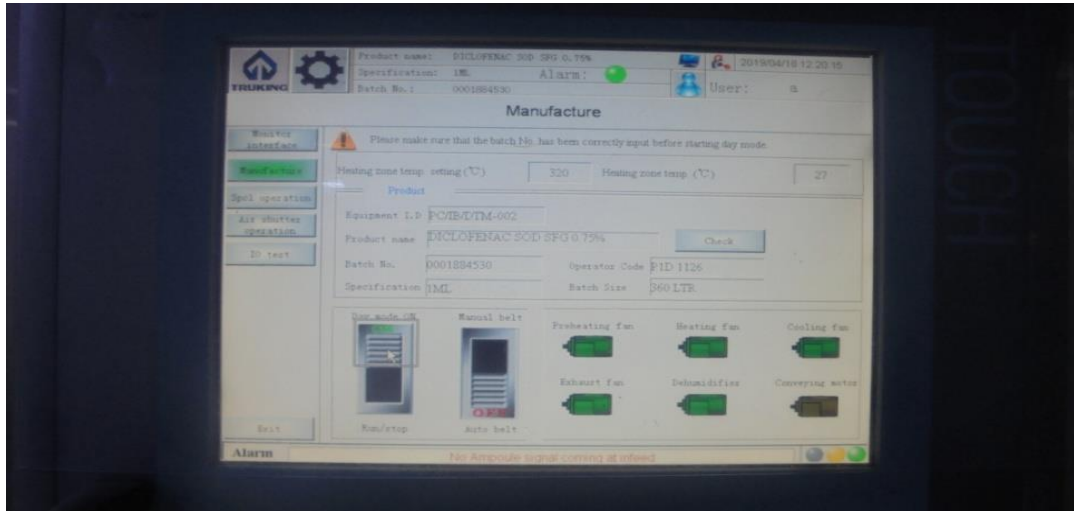
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6.7.2.2 Check the pressure value of each pressure gauge meets the requirements of following table as determined through validation:

6.7.2.2.1 DP between up and down of the filter pre-heating zone: 05-10 Pascal.

6.7.2.2.2 DP between up and down of the filter heating zone: 06-12 Pascal.

6.7.2.2.3 DP between up and down of the filter cooling zone: 05-10 Pascal.

6.7.2.2.4 DP between preheating zone and room: 05-10 Pascal.

6.7.2.2.5 DP between heating zone and room: 06-12 Pascal.

6.7.2.3 Place the ampoule retaining zone in the inlet of preheating zone.

6.7.2.4 When the temp in middle of the heating zone rises to setting value, start the washing machine.

6.7.2.5 When the ampoules pass through the air shutter and keep the air shutter from the ampoule mouth at 5 mm.

6.7.2.6 When the ampoules leave from the high temperature zone, start the air shutter of preheating zone and cooling zone and keep the air shutter part from the ampoule mouth at 5 mm.

6.7.2.7 When the ampoules leave from cooling zone, inform the filling operator to adjust the air shutter 5 mm higher than side plate.

6.7.2.8 When production ends, stop the Tunnel machine. Click the touch screen and access to main interface.

6.7.2.9 Click the button manufacture access to the interface and click the button manual ampoule conveying.

6.7.2.10 When the belt is running manually, put the ampoule pushing plate on to conveying plate on to the conveyor plate.



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6.7.2.11 When the pushing plate access to heating zone, close the air shutter in the joint of pre heating zone and heating zone, which is 10mm higher than side plate.

6.7.2.12 When the pushing plate leaves from the heating zone close the shutter in the joint of heating zone, which is 10 mm higher than side plate.

6.7.2.13 When the pushing plate leaves from the cooling zone inform the filling operator to adjust the air shutter at lowest position.

6.7.2.14 Close the daytime start and stop the mode of manual conveying ampoule.

6.7.2.15 The machine will reduce the temperature automatically; it will access the night mode of night start until 100 degree.

6.8 MACHINE CHANGEOVER SETTING: The machine changeover is carried out through **Manual shutter** adjustments. The changeover parameter are as below:

S.No.	Size of Ampoules	Height of Shutter
1.	1 ML	70 mm
2.	2 ML	80 mm
3.	3 ML	90 mm
4.	5 ML	100 mm

6.8.1 Procedure for Handling Tunnel Excursion:

S.No.	Excursions	Procedure for Handling
1.	Low Differential pressure	<ol style="list-style-type: none">1. Stop the filling activity.2. Remove the ampoules from tunnel3. Inform the engineering department about the issue.4. Approach QA and operate as instructed.
2.	Low tunnel temperature	<ol style="list-style-type: none">1. Stop the filling activity.2. Inform the engineering department about the issue.3. Wait for optimum temperature & then operate.
3.	Power supply failure	<ol style="list-style-type: none">1. The machine will stop.2. Remove the ampoules from tunnel.3. Inform the engineering department about the issue.4. Approach QA and operate as instructed.
4.	High Differential pressure	<ol style="list-style-type: none">1. Stop the filling activity.2. Inform the engineering department about the issue.3. Inform engineering department through maintenance request form and then initiate the incident as per current version of SOP.
5.	High tunnel temperature	<ol style="list-style-type: none">1. Stop the filling activity.



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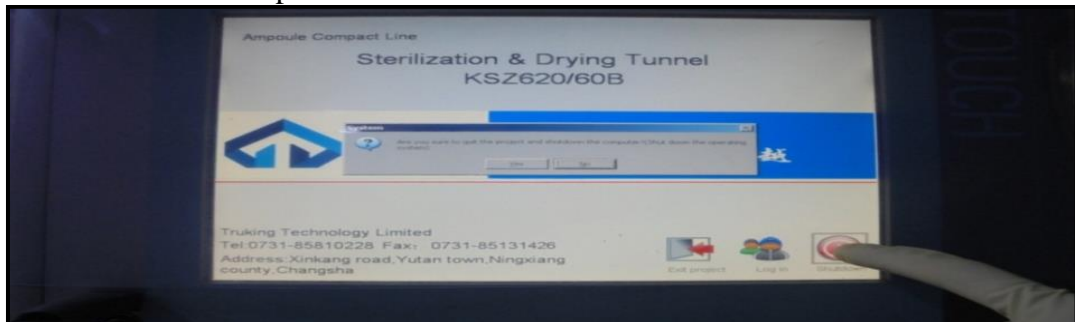
S.No.	Excursions	Procedure for Handling
		<ol style="list-style-type: none">2. Inform the engineering department about the issue.3. Wait up to temperature meeting as per specification and then restart the filling activity.

6.8.2 Remedial action plan: (In case of incident refer to SOP- Handling of Incident and close the incident accordingly)

6.8.2.1 Procedure for emergency: In case of any emergency, press the button of mushroom head emergency stop, then machine will stop immediately. It will cause immensurable damage to machine and electric condition.

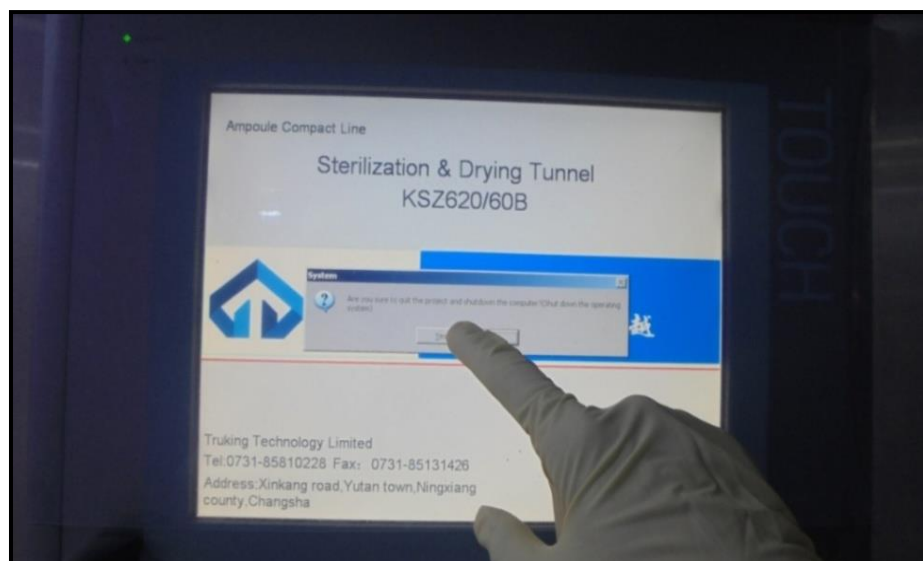
6.8.3 Procedure for Tunnel Shutdown after Washing:

6.8.3.1 Select the **shutdown** option from HMI:



6.8.3.2 YES/NO dialog box appears on the screen

6.8.3.3 Select the **YES** option.



6.8.3.4 The system is shut down and operation is completed.



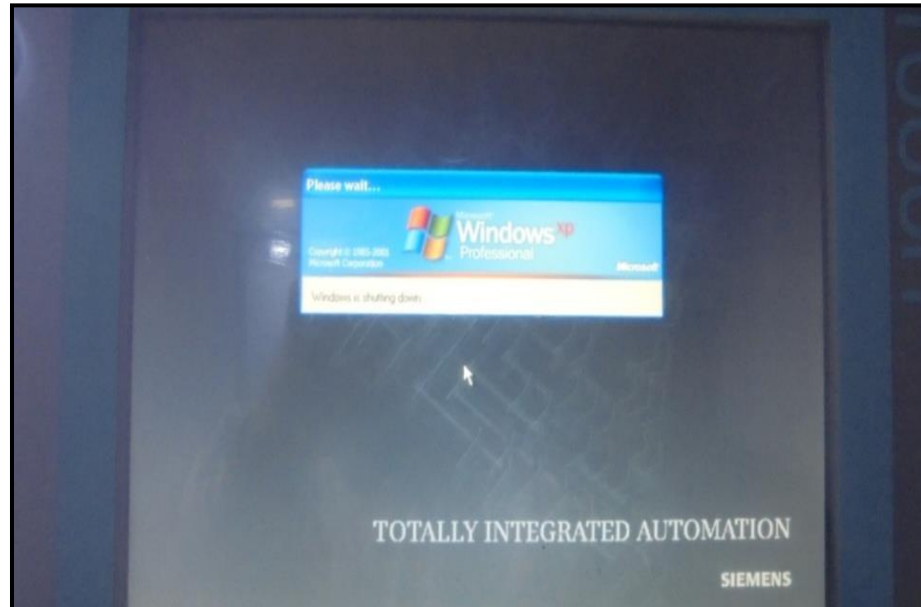
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6.8.4 Daily Cleaning:

- 6.8.4.1 Clean the outer surface of tunnel throughout the tunnel with 70% IPA solution with lint free cloth.
- 6.8.4.2 Cleaning of the tunnel shall be carried out end of the operation and end of the day.
- 6.8.4.3 Main switch of the control panel of the tunnel.
- 6.8.4.4 Allow the tunnel to cool down up to room temperature.
- 6.8.4.5 Ensure the shutter of the tunnel from the side of ampoule filling room is closed.
- 6.8.4.6 Run the conveyor and visually inspect the conveyor presence of any glass pieces. If any glass pieces place the vacuum cleaner at in feed zone and clean the conveyor.
- 6.8.4.7 Remove dirt and dust particles from the conveyor belt and surrounding using 70% IPA solution with lint free cloth.
- 6.8.4.8 Clean the outer surface throughout the tunnel with 70% IPA solution with line free cloth.
- 6.8.4.9 Stop the conveyer rotation clean the tunnel outer surface using dry lint free Mop.
- 6.8.4.10 Update the Equipment status board as per activity.
- 6.8.4.11 Record the details of cleaning operation in the equipment usage log.

6.8.5 Procedure for CIP of Tunnel:

- 6.8.5.1 First open the **purified water valve** from the utility pendant.



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6.8.5.2 Afterwards open the compressed air valve from the utility pendant.



6.8.5.3 Open the **purified & compressed air valve** located at bottom of tunnel.



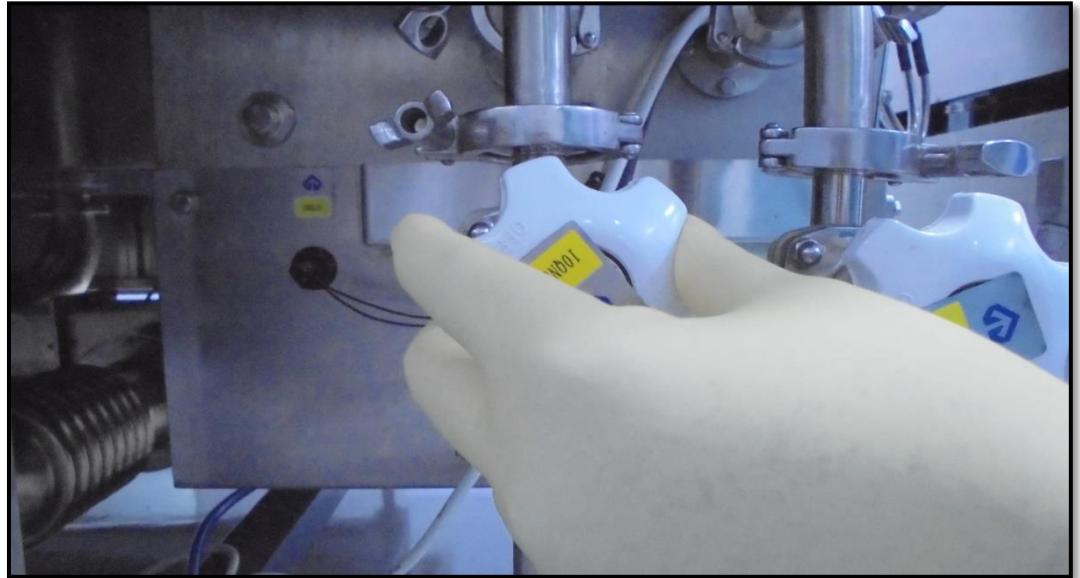
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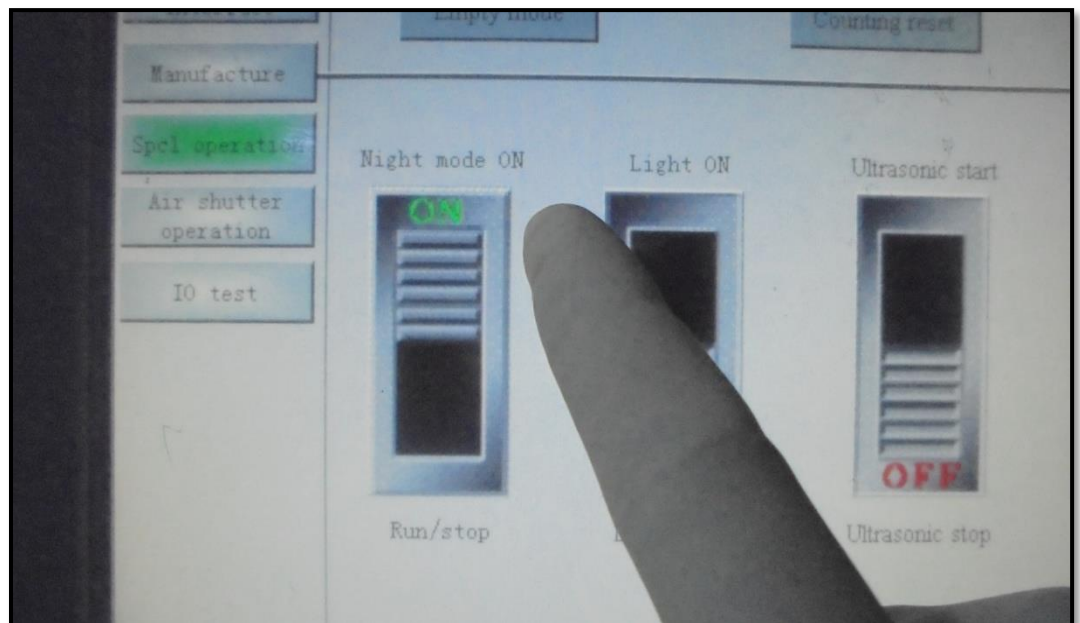
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6.8.5.4 Click the **special operation** option on the HMI.



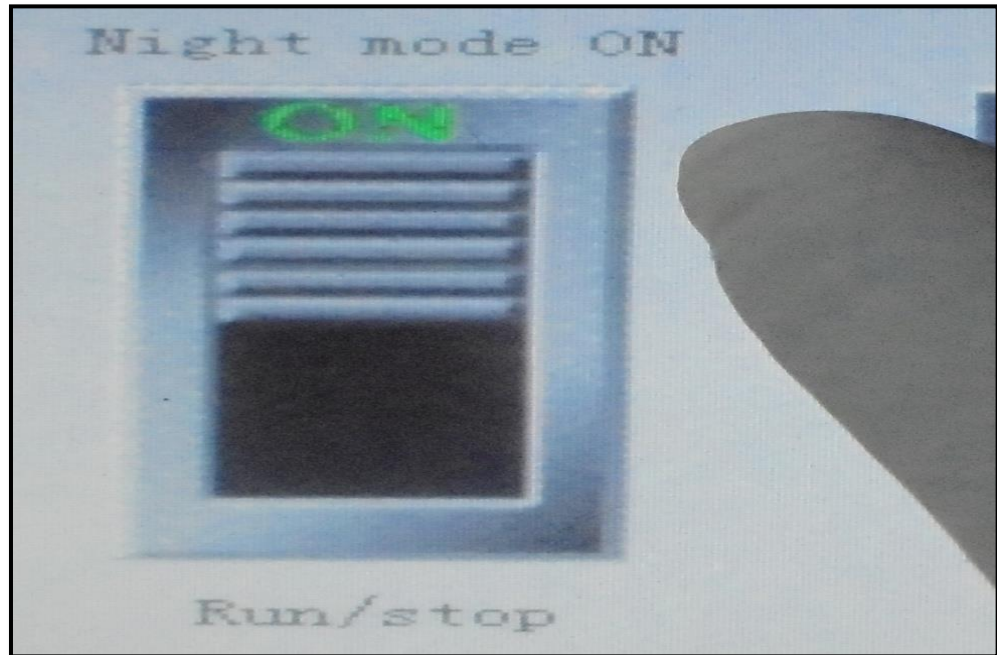
6.8.5.5 Click the **night mode** option. (Night mode conserves energy and cools down tunnel):



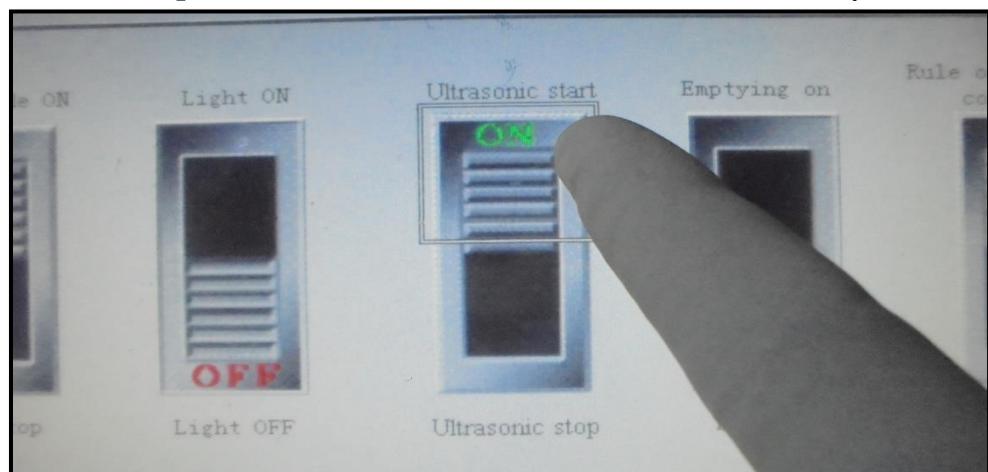
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6.8.5.6 Click the **ultrasonic option**. (Ultrasonic mode is used to vibrate the conveyor belt):



6.8.5.7 Click the **emptying on** option. (Emptying on removes glass particles and dust from conveyor)



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9.0 REFERENCES:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By



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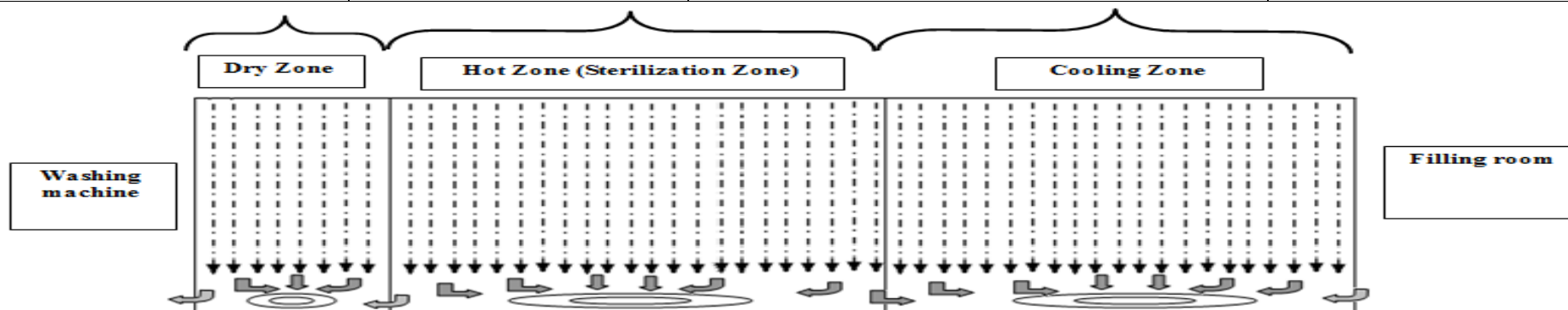
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ANNEXURE -I

CONFIGURATION & PARAMETER DETAILS OF STERILIZING AND DE-PYROGENATING TUNNEL DETAILS (AMPOULE)

Equipment ID.:	Model :	Manufacturer's Name: Truking Technologies Ltd.	Conveyor Width : 620 mm
Total Conveyor Length: 4200 mm	Dry zone Length : 610 mm	Hot Zone (Sterilization Zone) : 1800 mm	Cooling zone Length : 1790 mm



Parameter	Dry Zone	Hot Zone (Sterilization Zone)	Cooling (Stabilizing) Zone	Pack size	Ampoule Diameter	Conveyor speed
Velocity	90-110 feet/min	120-150 feet/min.	90-110 feet/min.	1 ml	10.5mm	76 mm/min.
DP	05-10Pa	6-12Pa	05-10Pa	2 ml	11.5mm	92 mm/min.
Temp.	80°C	320°C	40 to 50°C	3 ml	12.5mm	110 mm/min.
No. of HEPA	02	03	02	5 ml	14.5mm	120 mm/min.

